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Guidance For Industry

Animal Proteins Prohibited From Animal Feed; Small Entity Compliance Guide

This compliance guide is intended to help small entities comply with the final rule prohibiting the use of protein derived from mammals (with certain exceptions) in the feed of ruminants, (Federal Register of June 5, 1997, 62 FR 30936). This guide is being issued under section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996.

This guide represents the agency's current thinking on compliance with the final rule. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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ANIMAL PROTEINS PROHIBITED FROM RUMINANT FEED
SMALL ENTITY COMPLIANCE GUIDE

The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This guide represents the agency's current thinking on compliance with the regulation 21 CFR 589.2000 "Animal Proteins Prohibited from Ruminant Feed." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

I. Purpose and Scope of the Regulation

FDA adopted 21 CFR 589.2000 to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States through feed, and thereby minimize any risk to animals and humans.

The regulation generally prohibits the use of protein derived from mammals in ruminant animal feed. There are certain exceptions to this prohibition, however. Persons may decide whether to feed the following protein material from mammals to ruminants because they are excluded from the regulation's definition of "protein derived from mammalian tissues":

- o pure porcine (swine) or pure equine (horse) protein
- o blood and blood products
- o gelatin
- o inspected meat products which have been cooked and offered for human food and further heat processed for animal feed use
- o milk products (milk and milk proteins)

These materials are referred to as “nonprohibited material” throughout this guide. “Nonprohibited material” also includes protein derived from poultry, marine, and vegetable sources. All other mammalian protein sources are “prohibited material”.

"Ruminant animals" includes all four-stomached animals such as cattle, sheep, goats, buffalo, elk and deer.

"Inspected meat products which have been cooked and offered for human food and further heat processed for animal feed use" includes plate waste and used cellulosic food casings. It does not include trimmings from slaughter operations or butchers.

Persons may decide whether to feed products such as tallow and other fats to ruminants, even if they are derived from mammalian animals, because they are not protein products.

The regulation establishes certain requirements for:

- o renderers
- o protein blenders
- o feed manufacturers
- o distributors (including haulers)
- o individuals and establishments that are responsible for feeding ruminant animals

The following sections discuss the responsibilities of those who are included in the above five categories, and provide guidance for meeting the responsibilities.

Haulers are included in the definition of distributors. Distributors that haul both prohibited material and nonprohibited material (unblended or blended) are subject to the separation or clean-out procedures contained in sections II. and III. below.

Effective date. The final rule is effective on August 4, 1997. With regard to printed packaging, labels, labeling, and finished products manufactured before August 4, 1997, such material and products may continue to be used until those supplies are exhausted, but may not be used after October 3, 1997.

II. Requirements and Guide for Renderers

A. Definition of "Renderer"

The regulation defines "renderer" to mean any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. This includes parts of animals. The definition includes:

- establishments traditionally considered to be renderers; that is, those that process animal material into commercial products such as meat and bone meal;

- those who collect slaughter byproducts, etc. and subject them to minimal processing “such as dehydration” before offering the material for use in animal feed;

- those who collect and distribute slaughter byproducts, etc. to firms other than renderers that may intend the products to be used in animal feed. In this situation, the slaughter byproducts, etc. would be intended to be fed to animals without any processing; and

- renderers that also blend animal protein products. The blending operations of these renderers are subject to the same requirements for blenders as described under III. below.

B. Requirements and Guide

Firms that are excluded. Some firms that come within the definition of "renderer" are not subject to any of the specific requirements of the rule, because they do not process any prohibited material. This includes packer/renderers that process only material from swine, equine, and other nonprohibited species such as poultry and marine species. (Packer/renderers are renders that are associated with large slaughterhouses and process only the material that comes from those slaughter facilities). However, if these firms use prohibited material in ruminant feed, the feed would be adulterated. This may occur, for example, if a swine packer/renderer accepted cattle protein material into its rendering operation but did not comply with the regulations.

The regulation provides rules for two categories of renderers that do process prohibited material: Those that do not separate prohibited material from nonprohibited material, and those that do. Requirements and guide for each category follow:

1. Renderers that do not separate prohibited material from nonprohibited material

This category includes:

o Independent renderers. These firms obtain their raw material from a variety of sources, and may not be able to determine the species of some incoming material. Thus, the regulation states that products sold by these firms "contain or may contain" prohibited material. However, this category also includes independent renderers that may be able to determine the species of all their incoming material, but choose not to separate prohibited material from nonprohibited material.

o Packer/renderers who process or distribute prohibited material i.e. cattle packer/renderers.

a. Basic requirements. The regulation places three requirements on firms in this category. The firms are required to:

1) Label all products that contain or may contain prohibited material with the following cautionary statement: "**Do not feed to cattle or other ruminants**."

Only products that contain or may contain prohibited material are subject to this requirement. Therefore, products consisting solely of the material that are excluded from the definition of "protein derived from mammalian tissues" do not have to contain this statement. The material excluded from the definition are those listed in "I. Purpose and Scope of the Regulation."

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that any cautionary statement such as “Do not feed to cattle or other ruminants” be placed prominently on the label or labeling. The law requires the statement to be conspicuous so that the statement is likely to be read and understood under usual conditions of purchase and use. The agency suggests that the statement be distinguished by different type size or color, or by other means of highlighting the statement so that it is easily noticed by the user.

For bulk products, the statement should appear on the invoice and placard that accompany the shipment, and on any other labeling for the product. For products that are in bags or other containers, the statement should appear on product labels. These labels might be attached to, or be part of, the bag or other container. The statement should be on any other labeling for the product. "Labeling" includes leaflets, brochures, and other material whether or not they physically accompany the shipment of the product.

2) Maintain records sufficient to track the material throughout their receipt, processing, and distribution, and make them available for inspection and copying by the FDA.

This requirement can be satisfied by an invoice or other similar document reflecting receipt or purchase and sale or delivery of the product by the renderer. The document should contain information normally expected to be included in such documents, i.e.:

- date of the receipt or purchase and sale or delivery
- name and address of the seller
- name and address of the consignee
- identification of the product
- quantity

With regard to "identification of the product," FDA notes that invoices or similar sales documents may serve as the labels for bulk rendered products. The FFDCA generally requires that the label of a regulated product contain the product's common or usual name. The common or usual names of rendered products typically are those included in definitions published by the Association of American Feed Control Officials, Inc. (AAFCO), such as "meat and bone meal." Thus, the use of the common or usual name on the invoice or similar sales document will satisfy, in part, the "records" requirement of the regulation as well as the "common or usual name" requirement of the FFDCA.

3) Maintain the records for a minimum of one year.

The records used by the renderer to meet the records requirement, whether sales invoices or other documents, must be maintained so that they are legible and readily retrievable for FDA inspection and copying. The "one year" requirement means one year from the date of shipment of the product on products shipped in and shipped out.

b. Exemptions. The regulation provides for two levels of exemption from the cautionary statement and records requirements:

1) Renderers can be exempted from both the cautionary statement and records requirements if they do any one of three things:

*a) Use exclusively a manufacturing method that has been validated by FDA to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) (BSE is a TSE) and whose design has been made available to the public;

*b) Use routinely a test method that has been validated by the FDA to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Products found by such test to contain the agent that causes TSE's must carry the cautionary statement and continue to be subject to the records requirement. Records of the test results shall be made available for inspection by the FDA; or

*c) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by FDA.

*2) Renderers can be exempted from the records requirement alone if they use a permanent method, approved by FDA, to indicate that the product contains or may contain prohibited material. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the FDA and whose design has been made available to the public.

*NOTE: The FDA has not validated any methods that would meet the requirements for any of the above exemptions. If and when the agency does, it will provide additional guides as needed for the implementation of such exemptions.

2. Renderers that separate prohibited material from nonprohibited material

These requirements apply to renderers that separate prohibited material from nonprohibited material. Such firms might, for example, manufacture two types of products: (1) products that contain or may contain prohibited material, and (2) products that contain only pure swine protein, pure equine protein, poultry protein, marine protein, and/or other nonprohibited material. The first category includes swine or equine, poultry, or other nonprohibited material commingled with prohibited material.

a. Basic requirements. Renderers that separate prohibited and nonprohibited material are required to:

1) Include the cautionary statement "**Do not feed to cattle or other ruminants**," and provide the records as described in the section for "Renderers that do not separate prohibited material from nonprohibited material," section II.B.1.a. above.

The cautionary statement is required only for products that contain or may contain prohibited material.

2) Obtain nonprohibited animal source material only from single species slaughter facilities.

"Single species slaughter facilities" are those that are dedicated solely to the slaughter of a single species. Thus, firms that slaughter different species on different days or different shifts would not qualify as suppliers. However, the renderer could purchase nonprohibited animal source material from more than one single-species facility. For example, the renderer could purchase swine, equine, poultry, and/or marine from facilities that slaughter or process only those species. The renderer could commingle the protein from pure swine, pure equine, and one or more of the other nonprohibited animal source material.

3) Provide for measures to avoid commingling or cross-contamination of prohibited material and nonprohibited material. This can be done by:

a) Maintaining separate equipment or facilities for the manufacture, processing, blending or storage of such material; or

b) using clean-out procedures or other means adequate to prevent carry-over of prohibited material into animal proteins or feeds that may be used by ruminants. Examples of clean-out procedures that may be used to meet this requirement are included in Attachment A.

4) Maintain written procedures that document the measures described in item 3 above.

This means written procedures that specify the clean-out procedures and the procedures for separating prohibited material from nonprohibited material from the time of receipt until time of shipment. FDA advises that written procedures should be drafted

in sufficient detail to provide an understanding of the procedures being used to satisfy the regulations. The written procedures should also enable the investigator to take the written procedures into the plant and easily identify operations and processes stated in the written procedures. The written procedures should correspond to the facility's actual operations.

b. Exemptions. Renderers that separate will be exempted from the requirements listed above, as appropriate, if they meet the appropriate criteria for exemption as described in "Renderers that do not separate prohibited material from nonprohibited material," section II.B.1.b., above.

c. Haulers are included in the definition of distributors. Haulers who haul both prohibited material and nonprohibited material are required to comply with the separation or clean-out procedures in 3) and 4) above. For examples of clean-out procedures that may be used to meet the clean-out requirement, haulers should refer to the principles contained in Attachment B.

III. Requirements and Guide for Protein Blenders, Feed Manufacturers, and Distributors

A. Definitions

1. "Protein Blender" means any firm or individual that obtains processed animal protein from more than one source or from more than one species and subsequently mixes (blends) or redistributes an animal protein product. Thus, "blenders" under the regulation are protein blenders that are intermediaries between renderers and feed manufacturers. The distribution activities of blenders are included in this definition.

2. "Feed manufacturer" includes manufacturers of complete and intermediate feeds intended for animals. It includes on-farm and off-farm operations. The term includes pet food manufacturers, but, as explained below, pet food products are exempt from the labeling requirement under certain circumstances.

3. "Distributor" includes any firm or individual that distributes or transports feeds or feed ingredients intended for animals. The distribution activities of renderers, blenders, and feed manufacturers are included in this definition.

> Haulers are included in the definition of distributors. Haulers who haul both prohibited material and nonprohibited material including blended animal protein products are subject to the separation or clean-out procedures described below. Haulers of complete and intermediate feeds are "distributors."

B. Requirements and Guide

Firms that are excluded. Some firms covered by the definition of "feed manufacturer," and "distributor," and “blender” are not subject to any of the specific requirements of the regulation because they do not manufacture or distribute protein products or feed that contain or may contain prohibited material. These would include firms that handle only nonprohibited material. However, if these firms use prohibited material in ruminant feeds, the feed would be adulterated.

The regulation provides rules for two general categories of protein blenders, feed manufacturers and distributors.

1. Protein blenders, feed manufacturers and distributors that do not separate prohibited material from nonprohibited material

a. Basic requirements. The regulation requires firms in this category to:

1) label all products that contain or may contain prohibited material with the following cautionary statement: "**Do not feed to cattle or other ruminants**."

a) This requirement does not apply to pet food products that are sold or intended for sale at retail or feeds for nonruminant laboratory animals. However, if the pet food products or laboratory animal feed are sold or are intended for sale as distressed or salvage items, then such products are required to be labeled with the cautionary statement.

b) Labeling for all other animal feeds is required to contain the cautionary statement, including feeds intended for nonruminant animals.

c) The cautionary statement must be placed prominently on the label and labeling. The statement must be conspicuous so the statement is likely to be read and understood under usual conditions of purchase and use. The agency suggests that the statement be distinguished by different type size or color, or by other means of highlighting the statement so that it is easily noticed by the user.

d) For bulk products, the statement should appear on the invoice and placard that accompany the shipment, and on any other labeling for the product. For products that are in bags or other containers, the statement should appear on product labels. These labels might be attached to, or be part of, the bag or other container.

e) The statement should be on any other labeling for the product. "Labeling" includes leaflets, brochures and other material whether or not they physically accompany the shipment of the product.

2) maintain records sufficient to track the material throughout its receipt, processing, and distribution, and make them available for inspection and copying by the FDA.

This requirement can be satisfied by an invoice or other similar document reflecting receipt or purchase and sale or delivery of the product by the firm. The document should contain information normally expected to be included in such documents, i.e.:

- date of the receipt or purchase and sale or delivery
- name and address of the seller
- name and address of the consignee
- identification of the product
- quantity

With regard to "identification of the product," FDA notes that invoices or similar sales documents may serve as the labels for bulk rendered products. The FFDCA generally requires that the label of a regulated product contain the product's common or usual name. The common or usual names of rendered products typically are those included in definitions published by the Association of American Feed Control Officials, Inc. (AAFCO), such as "meat and bone meal." Thus, the use of the common or usual name on the invoice or similar sales document will satisfy, in part, the "records" requirement of the regulation as well as the "common or usual name" requirement of the FFDCA.

FDA acknowledges that its regulations permit feed labels to use collective terms, rather than common or usual names, in certain circumstances. For example, "animal protein products" can be used where the product contains certain ingredients such as meat and bone meal. The agency will not object to continued use of collective terms, provided that feed intended for ruminants does not contain protein from prohibited material.

NOTE: For on-farm mixers, production records can be substituted for sales invoices

3) Maintain the records for a minimum of one year.

The records used by the renderer to meet the records requirement, whether sales invoices or other documents, must be maintained so that they are legible and readily retrievable for FDA inspection and copying. The "one year" requirement means one year from the date of shipment of the product on products shipped in and shipped out.

b. Exemptions. The regulation provides for two kinds of exemptions from the cautionary statement and records requirements:

1) Protein blenders, feed manufacturers, and distributors can be exempted from both the cautionary statement and records requirements if they:

*a) purchase animal protein products from renderers that certify compliance with the validated deactivation method, test method or risk minimization method described in the renderers section, above;

*b) purchase animal protein products from parties that certify that they, in turn, purchased the products from renderers that so certified; or

*c) comply with these exempting provisions.

2) Protein blenders, feed manufacturers and feed distributors can be exempted from the records requirement if they:

*a) purchase animal protein products that are marked as described in the renderers section above;

*b) purchase animal protein products from renderers that certified compliance with the marking provisions;

*c) purchase animal protein products from parties that certify that they, in turn, purchased the products from renderers that so certified; or

*d) comply with the marking provisions.

Copies of the certifications are required to be made available for inspection and copying by FDA for one year after date of guaranty.

*NOTE: The FDA has not validated any methods that would meet the requirements for any of the above exemptions listed in b 1) or b 2). If and when the agency does, it will provide additional guides as needed for the implementation of such exemptions.

2. Protein blenders, feed manufacturers, and distributors that separate prohibited material and nonprohibited material

a. Basic requirements. The regulation requires firms in this category to:

1) Include the cautionary statement "**Do not feed to cattle or other ruminants**," and provide the records as described in the section for "Protein blenders, feed manufacturers, and distributors that do

not separate prohibited material and nonprohibited material," III.B.1.a., above.

The cautionary statement is required only for the products that contain or may contain prohibited material.

2) Provide for measures to avoid commingling or cross-contamination of prohibited material and nonprohibited material by:

a) maintaining separate equipment or facilities for the manufacture, processing, blending or storage of such material; or

b) using clean-out procedures or other means adequate to prevent carry-over of prohibited material into animal proteins or feeds that may be used by ruminants. Examples of clean-out procedures that may be used to meet this requirement are summarized in Attachment B.

3) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating prohibited material from nonprohibited material from the time of receipt until time of shipment.

FDA advises that written procedures should be drafted in sufficient detail to give an FDA investigator a general understanding of the procedures being used to satisfy the regulations. The written procedures should also enable the investigator to take the written procedures into the plant and easily identify operations and procedures stated in the written procedures. The written procedures should correspond to the facility's actual operations.

b. Exemptions. Protein blenders, feed manufacturers, and distributors will be exempted from the requirements listed above, as appropriate, if they meet the appropriate criteria for exemption as described in "Blenders, feed manufacturers, and distributors that do not separate prohibited material from nonprohibited material," section III.B.1.b., above, page.

c. Haulers are included in the definition of distributors. Haulers who separate prohibited material and nonprohibited material are required to comply with the separation or clean-out procedures, in 2) and 3) above.

IV. Requirements and Guide for Establishments and Individuals That Are Responsible for Feeding Ruminant Animals

This provision applies to livestock operations that feed ruminants. The regulation applies to "establishments and individuals that are responsible for feeding ruminants." To further clarify, all responsible persons, in both large and small feeding operations, are subject to the regulation.

A. Requirements and Guide. Establishments and individuals responsible for feeding ruminants are required to:

1. Maintain copies of all purchase invoices for all feeds received that contain animal protein.

If a feed intended for ruminants contains animal protein, the protein can consist only of nonprohibited material. The regulation requires maintenance of invoices for all feeds containing animal protein, so that FDA can verify if necessary that the animal protein contained in the ruminant feed is from nonprohibited sources.

2. Maintain copies of labeling for feeds containing animal protein products that are received.

The agency recognizes that bulk shipments of feed are commonplace, and that labeling information typically is contained in the invoices for bulk shipments. In those instances, maintenance of the invoice is sufficient. If the only labeling for a bulk product is on a placard, the placard for each shipment should be retained. Feed may also be received in bags or other containers that have attached labeling. In those instances, the labeling should be removed and retained. However, maintenance of only one such labeling piece from each shipment that represents a different product is necessary. Finally, if the labeling cannot be removed from the bag or other container, maintenance of a representative bag or a transposed copy of the labeling information from a container that cannot feasibly be stored will suffice.

3. Make copies of the invoices and labeling available for inspection and copying by FDA.

4. Maintain the records for a minimum of one year.

The records should be kept so that they are legible and readily retrievable. The one year requirement means one year from the date of the receipt of the product.

B. Exceptions and explanatory information.

1. Feed and feed ingredients not containing animal proteins are not subject to the regulation.

2. On-farm mills are subject to the requirements in Part III, above, "Protein blenders, feed manufacturers and distributors."

3. Persons who feed or intend to feed prohibited material to ruminant animals are subject to regulatory action under the FFDCA. Regulatory action could include seizure of inventory, injunction against feeding prohibited material to ruminants, or prosecution.

ATTACHMENT A

Separating and Processing Options for Renderers

FDA is providing the following guidance for renderers.

PROCESSING OPTION #1

a. Appropriate for the following operation:

Single plant with two or more totally segregated processing lines. This includes all process functions from receiving raw material through and including finished product load-out.

Raw Material → Grinding → Cooking → Pressing → Meal Grinding → Storage → Load-Out

b. Suggested Clean-out Procedures for Processing Option 1

No clean-out procedures are necessary for this processing situation, as the lines are completely separate. This type of plant should have the ability to process prohibited material and nonprohibited material so long as procedures are in place to assure total segregation. These may be part of the plant's written procedures that specify how materials are to be segregated and be available for inspection and subject to review for compliance purposes.

PROCESSING OPTION #2

a. Appropriate for the following operation:

Single plant with two or more segregated raw material receiving, grinding, cooking, and pressing lines but sharing finished product conveying, grinding, and load-out systems.

Raw Material → Grinding → Cooling → Pressing ↘ ↗ Storage → Load-Out

Meal Grinding ↗ (and/or)

Raw Material → Grinding → Cooking → Pressing ↗ ↘ Storage → Load-Out

b. Suggested Clean-out Procedures for Processing Option 2

The clean-out and flushing guidelines for this type of plant deal specifically with the meal grinding (and screening),storage, and load-out systems. It is assumed that the plant would have separate storage facilities for prohibited material and nonprohibited material. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment from the first point of commonality of products to the final load-out device. The system should then be flushed with a sufficient volume of nonprohibited material to accomplish one complete change of operating volume of the entire system (exclusive of separate meal storage facilities). The flush material would be considered as prohibited material and treated as such.

Once the system has been flushed, all subsequent material processed would be nonprohibited material. Specific operating procedures would be documented and verified and would be part of the plant's written procedures specifying the clean-out procedures utilized and would be available for inspection and subject to review for compliance purposes.

PROCESSING OPTION #3

a. Appropriate for the following operation:

Single plant with separate raw material receiving and grinding, common cooking and pressing, common or separate finished product handling.

Raw Material → Grinding ↘

Cooking → Pressing → Meal Grinding → Storage → Load-out
↘ (and/or) ↗ (and/or)
Raw Material → Grinding ↗ → Meal Grinding → Storage → Load-out

b. Suggested Clean-out Procedures for Processing Option 3

The clean-out and flushing guide for this type of plant deal specifically with the cooking and pressing systems. The meal grinding, storage, and load-out systems should be cleaned and flushed according to the guide in processing option 2 above. It is also assumed that this type of plant would have separate storage facilities for prohibited material and

nonprohibited material. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment (including the cooker) from the first point of commonality of raw material to the meal grinding system. The system should then be flushed with sufficient nonprohibited material to accomplish the following changes of the operating volume of the cooker:

For a continuous cooker with a bottom discharge (to provide positive cooker clean-out), material equal to at least one half the operating volume of the cooker;

For a continuous cooker without a bottom discharge, material equal to at least the operating volume of the cooker; or

For a batch cooker system, material equal to at least one half the operating volume of the cooker for each batch cooker.

In general, the volume of material required to flush the cooking system should provide an adequate flush of the meal grinding, storage and load-out system, as well. The flush material should be considered prohibited material and treated as such. All subsequent material processed should be considered nonprohibited material. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the clean-out procedures utilized, and would be available for inspection and subject to review for compliance purposes.

PROCESSING OPTION #4

a. Appropriate for the following operation:

Single plant with one processing line. This includes all process functions from raw material receiving through and including product load-out.

Raw Material → Grinding → Cooling → Pressing → Meal Grinding → Storage → Load-out
↗ (and/or)
↘ Storage → Load-out

b. Suggested Clean-Out Procedures for Processing Option 4

The clean-out and flushing guidelines for this type of plant deal with the complete plant process. It is assumed that this type of plant would have adequate storage facilities to separate prohibited material from nonprohibited material. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system. As a guideline, the volume of flushing material should be equal to the operating volume of the process and transport equipment, including the cookers.

The flush material should be considered prohibited material and treated as such. All subsequent material processed would be considered nonprohibited material. Specific operating procedures should be documented and verified, be part of the plant's written procedures specifying the clean-out procedures utilized, and would be available for inspection and subject to review for compliance purposes.

SUMMARY FOR CLEAN-OUT PROCEDURES - RENDERERS

Due to the degree of variability among rendering systems, a Hazard Analysis Critical Control Point (HACCP) approach to process controls would be helpful in implementing any of the above clean-out procedures. This will enable differences to be addressed on a site-specific basis. Renderers could follow the above clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedures, including time and volume calculations, should be part of the plant's written procedures specifying the clean-out procedures utilized and would be available for inspection and subject to review for compliance purposes.

ATTACHMENT B

Separating and Processing Options for Blenders, Feedmills, Distributors, and Haulers

FDA is providing the following guidance for blenders, feedmills, distributors, and haulers. This guidance was adapted from the medicated feed GMP's. The medicated feed GMP's for clean-out were chosen as a model because they have proved to be effective in preventing unsafe drug carry-over into feed and thereby preventing tissue residue in products intended for human food. However, the medicated feed GMP's are not an entirely appropriate model for clean-out procedures for the rendering industry because of the difference in equipment and operating procedures. The agency will consider firms using the clean-out procedures at least as stringent as those detailed below to meet the requirement of "adequate" as used in the regulation.

> Adequate clean-out procedures for all equipment used in the manufacture and distribution of feeds containing prohibited material and nonprohibited material are essential to avoid unsafe contamination of ruminant feeds. Such procedures may consist of cleaning by physical means, e.g., vacuuming, sweeping, etc. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned either through use of a nonprohibited material product. After cleaning, the nonprohibited material used in the cleaning should be considered prohibited material and should be handled and stored in an appropriate manner.
>
> FDA suggests that for all equipment, including that used for storage, processing, mixing, conveying, and distribution that comes in contact with feeds containing prohibited material and nonprohibited protein, that reasonable and effective procedures to prevent contamination of manufactured feed be followed. The steps used to prevent contamination of feeds often include one or more of the following, or other equally effective procedures: (1) Physical means (vacuuming, sweeping, or), flushing, and/or sequential production of feeds; (2) if flushing is utilized, FDA recommends that the flush material be properly identified, stored, and used in a manner to prevent contamination of other feeds. The volume of the flushed material should be sufficient to equal the operating volume of the shared equipment; (3) if sequential production is utilized, FDA recommends that it be on a predetermined basis designed to prevent unsafe contamination of ruminant feeds. An example of appropriate sequencing would be producing a swine feed containing prohibited material, followed by a swine or poultry feed not using prohibited material, followed by a ruminant feed containing nonprohibited material.

Due to the degree of variability among feedmill systems, a HACCP approach to process controls would be helpful in implementing any of the above clean-out procedures. This will enable differences to be addressed on a site-specific basis. Feedmills could follow the clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedures, including time and volume calculations, may be part of the plant's written procedures specifying the clean-out procedures utilized, and the written procedures are subject to FDA review for compliance purposes.

END